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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/826,893	04/06/2001	Kjell Olmarker	003300-765	3406

7590

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EXAMINER

O HARA, EILEEN B

ART UNIT

PAPER NUMBER

1646

DATE MAILED: 05/23/2002

12

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/826,893

Applicant(s)

OLMARKER ET AL.

Examiner

Eileen B. O'Hara

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-29 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:  
  
Group I, claim(s) 1-19, drawn to a method for treating nerve disorders in a mammal, classified in class 514, subclass 2.  
  
Group II, claim(s) 20-29, drawn to pharmaceutical compositions comprising a TNF- $\alpha$  Inhibitor, classified in class 514, subclass 2.
2. Inventions II and I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the pharmaceutical compositions can be used to treat disorders other than nerve disorders.
3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Art Unit: 1646

This application contains claims directed to the following patentably distinct species of the claimed invention.

4. ***Group I***

If Group I is elected, Applicants must select one of the following species of TNF- $\alpha$  inhibitor: CDP-571, D2E7, CDP-870, CT3, ITF-2357, PD-168787, CLX-1100, M-PGA, NCS-700, PMS-601, RDP-58, TNF-484A, PCM-4, CBP-1011, SR-31747, AGT-1, Solimastat, CH-3697, NR58-3.14.3, RIP-3, Sch-23863 or SH-636.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claim is generic.

Additionally if Group I is elected, Applicants must also select one from the following species of nerve disorders to be treated: spinal disorder, nerve root injury, herniated discs, sciatica, nucleus pulposus-induced nerve injury or spinal cord compression.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1 and 19 are generic.

Applicant is required, in reply to this action, to elect a single species from each of the two types of species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any

Art Unit: 1646

claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

Claim 1 corresponds to the following species of TNF- $\alpha$  inhibitors: CDP-571, D2E7 and CDP-870.

Claim 19 corresponds to the following species of TNF- $\alpha$  inhibitors: CT3, ITF-2357, PD-168787, CLX-1100, M-PGA, NCS-700, PMS-601, RDP-58, TNF-484A, PCM-4, CBP-1011, SR-31747, AGT-1, Solimastat, CH-3697, NR58-3.14.3, RIP-3, Sch-23863 or SH-636.

Claims 5, 6, 7, 8, 10 and 11 correspond to the following species of nerve disorder: spinal disorder, nerve root injury, herniated discs, sciatica, nucleus pulposus-induced nerve injury and spinal cord compression. Claim 9 will be examined to the extent it corresponds to the elected nerve disorder.

The following claim(s) is generic for nerve disorder to be treated: 1 and 19.

Art Unit: 1646

5. ***Group II***

If Group II is selected, Applicants must select one from the species of TNF- $\alpha$  inhibitors: CDP-571, D2E7, CDP-870, CT3, ITF-2357, PD-168787, CLX-1100, M-PGA, NCS-700, PMS-601, RDP-58, TNF-484A, PCM-4, CBP-1011, SR-31747, AGT-1, Solimastat, CH-3697, NR58-3.14.3, RIP-3, Sch-23863 or SH-636.

Applicant is required, in reply to this action, to elect a single to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claim is generic.

The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

Claim 20 corresponds to the following species of TNF- $\alpha$  inhibitors: CDP-571, D2E7 and CDP-870.

Claim 29 is drawn to the following species of TNF- $\alpha$  inhibitors: CT3, ITF-2357, PD-168787, CLX-1100, M-PGA, NCS-700, PMS-601, RDP-58, TNF-484A, PCM-4, CBP-1011, SR-31747, AGT-1, Solimastat, CH-3697, NR58-3.14.3, RIP-3, Sch-23863 or SH-636.

Art Unit: 1646

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143). To be fully responsive, if Group I is elected, Applicants must select one species from each of the two types listed, TNF- $\alpha$  inhibitors and nerve disorder, and if Group II is elected, Applicants must select one species of TNF- $\alpha$  inhibitor.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara, whose telephone number is (703) 308-3312. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

Official papers Before Final filed by RightFax should be directed to (703) 872-9306.

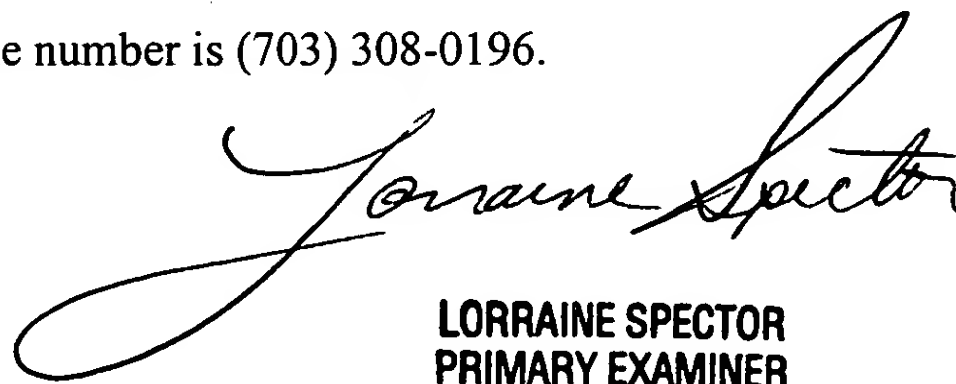
Official papers After Final filed by RightFax should be directed to (703) 872-9307.

Official papers filed by fax should be directed to (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Eileen B. O'Hara, Ph.D.

Patent Examiner



LORRAINE SPECTOR  
PRIMARY EXAMINER